SYNTHES®

FEB 2 7 2001

K003786

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Thomas M. Maguire
DEVICE NAME:	SMF Resorbable Meshes and Sheets
CLASSIFICATION:	Class II, 21 CFR 872.4760: Bone plate.
PREDICATE DEVICE:	MacroPore Protective Sheet
DEVICE DESCRIPTION:	SMF resorbable meshes and sheets are available in a range of sizes from 20 x 20 mm to 125 x 125 mm. The thickness of the mesh plates and sheets range from 0.50 mm to 2.0 mm. Pore sizes of the mesh plates range from 1.7 mm to 3.5 mm in diameter.
INTENDED USE:	SMF resorbable meshes and sheets are intended to facilitate healing in trauma, reconstruction and bone augmentation procedures of the mandible. The following specific indications are included: • to maintain the relative position of bony fragments in trauma and bone graft procedures; and • to contain and prevent migration and shifting of autograft, allograft and/or bone graft substitutes that may be necessary in reconstructive procedures. These devices are not intended for use in the spine. The devices are not intended for load bearing indications unless used in conjunction with traditional rigid fixation.
MATERIAL:	Poly(L/DL-lactide)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2001

Mr. Thomas M. Maguire
Project Leader, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301-1222

Re: K003786
Trade Name: SMF Resorbable Meshes and Sheets
Regulatory Class: II
Product Code: JEY
Dated: December 7, 2000
Received: December 8, 2000

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K003786

Device Name: SMF Resorbable Meshes and Sheets

Indications/Contraindications:

Synthes resorbable meshes and sheets are intended to facilitate healing in trauma, reconstruction and bone augmentation procedures of the mandible. The following specific indications are included:

- to maintain the relative position of bony fragments in trauma and bone graft procedures; and
- to contain and prevent migration and shifting of autograft, allograft and/or bone graft substitutes that may be necessary in reconstructive procedures.

These devices are not intended for use in the spine. The devices are not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003786